UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

MENTASTA TRADITIONAL COUNCIL, Individually and on behalf of a class of Federally-Recognized Indian tribes similarly situated within the boundaries of the State of Alaska,

Plaintiffs,

v.

ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC.; JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ALLERGAN FINANCE LLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; MALLINCKRODT BRAND PHARMACEUTICALS, INC.; SPECGX LLC; CARDINAL HEALTH, INC.;

No. _____

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

McKESSON CORPORATION; HEALTH MART SYSTEMS, INC.; AMERISOURCEBERGEN CORPORATION; WALGREEN CO.; ALBERTSONS COMPANIES LLC; WALMART INC.; and CVS PHARMACY, INC.

Defendants.

CLASS ACTION COMPLAINT
FOR SIMILARLY SITUATED FEDERALLY-RECOGNIZED
ALASKAN INDIAN TRIBES

1. The MENTASTA TRADITIONAL COUNCIL, a federally-recognized Indian Tribe, ("Mentasta Tribe"), individually and on behalf of all federally-recognized Alaskan Indian tribes that have not filed suit in the premises, brings this class action for injunctive relief, abatement, compensatory damages, punitive damages, civil penalties, and any other relief allowed by law and equity against the Defendants that, by their actions, have knowingly or negligently marketed and promoted prescription opioid drugs and have knowingly or negligently manufactured and distributed prescription opioid drugs within the Mentasta Tribe and other geographic areas controlled by said federally-recognized tribe in Alaska in a manner that foreseeably injured, and continues to injure, the Mentasta Tribe and its Tribal Citizens throughout the State of Alaska. The Mentasta Tribe also brings this Class Action Complaint for a class of Alaskan Indian tribes, as defined herein, for the establishment of an opt-in damages and injunctive relief class of similarly situated Alaskan Indian tribes.

2. The Defendants unleashed a devastating epidemic of prescription and non-prescription opioid abuse into federally-recognized Indian tribes, their peoples, and their Indian Lands across the United States, including Alaska. To date, not a single Defendant has indicated any responsibility for the prescription opioid epidemic in Indian Country. This is an epidemic of unprecedented proportion constituting an existential threat to Indian tribes, their Tribal Citizens, Indian Lands, and ways of life, causing a substantial loss of public and private resources, heartbreaking addiction, permanent disabilities, and tragic deaths. The ravaging effects that the opioid crisis has had on the babies and children born to addicted mothers in Indian Country are permanent, with effects ranging from Non-Abstinence Syndrome babies and children to utter depletion of foster care and educational resources. In a gross understatement, the former U.S. Surgeon General stated during his 2016 visit with tribal representatives the "prescription opioid epidemic that is sweeping across the U.S. has hit Indian Country particularly hard."

3. Notwithstanding the facts, allegations, and claims made herein by the Mentasta Tribe, as well as in pending civil actions filed by numerous other Indian tribes, not a single Defendant has agreed to enter into any settlement negotiations with any Indian tribes.

4. The Defendants through their essential distribution partner and co-conspirator McKesson Corporation ("McKesson") specifically targeted the American Indians/ Alaska Natives population susceptible to addictive substances. McKesson and the other Defendants knew that American Indians/Alaska Natives are at least two times more susceptible to opioid addiction than the rest of the U.S. population at large. McKesson and the other Defendants knew that American Indian high school students are three times more prone to try opioid pills than U.S. teenagers in general. McKesson and the other Defendants knew that American Indians/Alaska Natives are three times more likely to die from a drug overdose than the rest of the U.S. population. McKesson and

the other Defendants knew that American Indian Country lies in more rural areas where medically assisted addiction treatment is unavailable, underfunded, or overwhelmed by demand, such that opioid addiction treatment is too remote to be of any use.

5. McKesson has admitted in previous filings in order to gain federal jurisdiction over complaints filed by other federally-recognized Indian tribes in state courts that it, McKesson, was an integral part of spreading and distributing opioid prescription drugs into Indian Lands and to the Tribal Citizens of Indian tribes all over the United States, including Alaska. Integral to McKesson's grand scheme to addict American Indians/Alaska Natives to the Defendants' opioid prescription drugs were the coordinated conduct and actions of the opioid industry from opioid poppies being cultivated by certain Defendants to being manufactured by other Defendants.

6. The opioids epidemic is the necessary by-product of intentional and grossly negligent acts and conduct of the Defendant companies and the individual members of their Boards of Directors. Notwithstanding the known dangers of marketing opiates to American Indians/Alaska Natives, the Defendants employed long-running, deceptive, and deceitful marketing campaigns aimed directly at American Indians/Alaska Natives and carried out dutifully by McKesson, through advocating the drugs' expanded use while downplaying and misstating the dangers of opioid drugs, through allowing opioids to be diverted into improper channels to fuel the epidemic and profits, and through blind disregard for the effects that opiates would have on American Indians/Alaska Natives. This massive fraud and far reaching drug conspiracy, while yielding billions of dollars in profits for the Defendants, has caused the Mentasta Tribe to suffer the economic, human, and existential costs of increased health care expenditures, crime, cultural devastation, and social ills resulting from the cycle of prescription opioid abuse, addiction, diversion, and treatment. Some Defendants have even profited by creating drugs to combat the

effects of addiction that they created, thus creating for themselves a virtually closed loop of profits from cradle to grave.

7. Opioids have been a commercial triumph for Defendants due to deceptive marketing. Defendants have obscured facts that prescription opioids are dangerous and addictive when used for general pain management and relief. Defendants deliberately pressed a narrative about opioids devoid of scientific support to encourage the use of opioids by those suffering from common chronic pain conditions.

8. Defendants' scheme has led to the vast overprescribing, distribution, and diversion of prescription opioids.

9. Defendants have willfully turned a blind eye to known or knowable problems, including diversion, in their own supply chain. Defendants created conditions in which vast amounts of opioids have flowed freely from Defendants' manufacturing facilities to wholesale distributors, fed through doctors and retail pharmacies, and on to abusers and drug dealers, with Defendants filling suspicious orders from distributors and pharmacies while consciously ignoring "red flags" in the amount and concentration of orders for opioids that require further investigation and resolution before distributing the pills into the regulated controlled-substances supply chain.

10. Defendants have caused massive amounts of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the Mentasta Tribe. This is the phenomenon known as "opioid diversion." Acting against their common law duties, through both illegal marketing and opioid diversion, Defendants have created an environment in which drug diversion can flourish. As a result, unauthorized opioid users in and around the Mentasta Tribe and similarly situated Indian tribes throughout Alaska have ready access to illicit sources of diverted opioids.

11. Defendants have caused foreseeable damages to the Mentasta Tribe and similarly situated Indian tribes throughout Alaska, including the costs of providing: (1) medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths and burial and funeral expenses; (2) counseling and rehabilitation services; (3) treatment of infants born with opioid-related medical conditions, particular Non-Abstinence Syndrome babies, children, and adolescents; (4) welfare for children whose parents suffer from opioid-related disability or incapacitation; (5) law enforcement and public safety relating to the opioid epidemic within the Mentasta Tribe and similarly situated Indian tribes throughout Alaska; and (6) increased crime, property damage, and public blight within the Mentasta Tribe and similarly situated Indian tribes throughout Alaska caused by opioids. Mentasta Tribe and Indian tribes throughout Alaska have suffered substantial damages relating to the lost productivity of their Tribal Citizens, businesses, and their ability to govern.

12. Mentasta Tribe and similarly situated Indian tribes throughout Alaska have been left out of major initiatives by state governments, municipal governments, county governments, and the federal government in attempts to remedy the opioid crisis. Mentasta Tribe and similarly situated Indian tribes did not share in any of the State Government civil recoveries and/or criminal penalties paid by some Defendants and other opioid manufacturers. Mentasta Tribe and other similarly situated Indian tribes did not enter into any consent judgments with any opioid manufacturers, like most State Governments. Unlike State Government authorities, Indian tribes never had access to the ARCOS database. Unlike State Government authorities, Indian tribes are without the police and prosecution power to have taken steps against pill mills, overprescribing doctors, opioid diversion, and other wrongful and illegal acts related to the opioid epidemic.

13. Indian tribes are not state governmental subdivisions of any state, in contrast to municipalities and counties. This Class Action Complaint seeks to protect the sovereign rights of all federally recognized Tribes in Alaska and their Tribal Citizens who have been harmed by the opioid epidemic and who may not have the resources required to prosecute an individual claim in the opioid litigation, as well as establishing a negotiating Class of Alaskan Indian tribes for purposes of pursuing adequate and reasonable remedies as against the Defendants.

PARTIES

Plaintiff

14. The Mentasta Traditional Council (or "Mentasta Tribe") is a federally recognized sovereign Indian tribe. It is governed by the Mentasta Traditional Council Constitution and the laws of the Mentasta Traditional Council and exercises inherent governmental authority within the Mentasta Tribe. The Mentasta Tribe is part of the Mt. Sanford Tribal Consortium of two federally recognized Tribal Councils. The Mentasta Traditional Council brings this action in the exercise of its powers on behalf of the Mentasta Tribe in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all Mentasta Tribal Citizens. In particular, the Mentasta Traditional Council brings this action to stop the growing prescription opioid epidemic within the Mentasta Tribe and all other Alaskan Indian tribes as a class to recover damages and seek other redress for harm caused by both Defendants' improper marketing and promotion practices relating to prescription opioids and by Defendants' improper manufacturing, distribution, and reporting practices relating to prescription opioids. Defendants' actions have caused, and continue to cause, a crisis that threatens the health, safety, and welfare of the Tribal Citizens of the Mentasta Traditional Council.

15. The Mentasta Tribe brings this action in the exercise of its powers on behalf of the Mentasta Tribe in their proprietary capacity and under its *parens patriae* authority in the public

interest to protect the health, safety, and welfare of all respective Mentasta Tribe's Tribal Citizens, adults and children. In particular, the Mentasta Tribe brings this action to stop the growing prescription opioid epidemic within the Mentasta Tribe and similarly situated Indian tribes throughout Alaska and to recover damages and seek other redress for harm caused by both Defendants' improper marketing and promotion practices relating to prescription opioids and by Defendants' improper manufacturing, distribution, and reporting practices relating to prescription opioids. Defendants' actions have caused, and continue to cause, a crisis that threatens the health, safety, and welfare of the Tribal Citizens of the Mentasta Tribe.

16. The Mentasta Tribe further seeks to protect the rights of other similarly situated, federally recognized Tribes located within the boundaries of the State of Alaska. The Mentasta Tribe, however, acknowledges the sovereign rights of each and every Alaska Tribe such that it is bringing the class action part of this Complaint as a voluntary class, rather than an involuntary or opt-out class.

Manufacturer Defendants

17. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013.

18. Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (Allergan Finance LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these

Defendants and entities is owned by Defendant Allergan PLC, which uses them to market and sell its drugs in the United States. Collectively, these Defendants and entities and their DEA registrant subsidiaries and affiliates which manufacture, promote, distribute, and sell prescription opioids nationally - including to the Mentasta Tribe and similarly situated Indian tribes throughout Alaska - are referred to as "Actavis."

19. Actavis manufactures or has manufactured generic versions of Kadian, Duragesic, and Opana as well as Norco.

20. Upon information and belief, Actavis made thousands of payments to physicians nationwide under the guise of post-marketing safety surveillance, business consulting services, and other services when in reality, the payments advanced a deceptive promotion campaign used to maximize the use of prescription opioids.

21. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

22. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

23. Teva and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids, including Actiq and Fentora, to the Mentasta Tribe and similarly situated Indian tribes throughout Alaska.

24. Upon information and belief, Cephalon made thousands of payments to physicians nationwide under the guise of post-marketing safety surveillance, business consulting services,

and other services when in reality the payments advanced a deceptive promotion campaign used to maximize the use of prescription opioids.

25. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

26. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

27. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly-owned subsidiary of J&J and J&J's manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

28. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania Corporation with its principal place of business in Titusville, New Jersey.

29. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

30. J&J, Janssen Pharmaceuticals, OMP, Janssen Pharmaceutica, and their DEA registrant subsidiaries and affiliates (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and to Plaintiffs. Among the drugs Janssen manufactures or manufactured are the following: Duragesic, Nucynta, and Nucynta ER.

31. Upon information and belief, Janssen made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact, these payments were used to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

32. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

33. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

34. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par Pharmaceutical") were acquired by Endo International plc. in September 2015. Par Pharmaceutical is an operating company of Endo International plc.

35. EHS, EPI, Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively "Endo") manufacture opioids sold nationally to the Mentasta Tribe and similarly situated Indian tribes throughout Alaska, including Opana ER, Opana, Percodan, Percocet, generic Oxycodone, generic Oxymorphone, generic Hydromorphone, generic Hydromorphone, and generic Hydrocodone.

36. Upon information and belief, Endo made thousands of payments to physicians nationwide under the guise of post-marketing safety surveillance, business consulting services,

and other services when in reality the payments advanced a deceptive promotion campaign used to maximize the use of prescription opioids.

37. Defendant Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, Surrey, United Kingdom. Within the United States, Mallinckrodt plc operates under the name Mallinckrodt Pharmaceuticals, and maintains its U.S. headquarters in Hazelwood, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Shares of Mallinckrodt plc are traded on the New York Stock exchange under the symbol "MNK." In its most recent Form 10-K filed with the United States Securities and Exchange Commission, Mallinckrodt plc stated that its products compete primarily in the U.S. market, which accounted for almost 90% of the company's $3.2 billion in net sales during the 2018 fiscal year.

38. Defendant Mallinckrodt LLC is a Delaware limited liability company with a principal place of business in Hazelwood, Missouri. Since June 28, 2013, Mallinckrodt LLC has been a wholly-owned subsidiary of Mallinckrodt plc. Prior to June 28, 2013, Mallinckrodt LLC was a wholly-owned subsidiary of Covidien plc.

39. Defendant Mallinckrodt Brand Pharmaceuticals, Inc. is a Missouri corporation with its principal place of business in Hazelwood, Missouri. Mallinckrodt Brand Pharmaceuticals operates as a subsidiary of Mallinckrodt plc, and is responsible for distributing generic opioids produced by Mallinckrodt plc and its subsidiaries.

40. Defendant SpecGx LLC is a Delaware limited liability company with a principal place of business in Clayton, Missouri. SpecGx was formed on November 14, 2016, as a wholly-owned subsidiary of Mallinckrodt LLC. Upon information and belief, SpecGx currently

manufactures and sells in the USA certain opioids that were previously manufactured by Mallinckrodt LLC.

41. Mallinckrodt, plc, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals, Inc., and SpecGx LLC are collectively referred to as "Mallinckrodt."

42. Mallinckrodt operates a vertically integrated business in the United States that imports raw opioid materials, manufactures opioid products, and markets and sells these products to drug distributors, retail pharmacy chains, and hospital buying groups.

43. Upon information and belief, Mallinckrodt made thousands of payments to physicians nationwide under the guise of post-marketing safety surveillance, business consulting services, and other services when in reality the payments advanced a deceptive promotion campaign used to maximize the use of prescription opioids.

44. Actavis, Cephalon, Janssen, Endo, and Mallinckrodt are collectively referred to as "Manufacturer Defendants."

Distributor Defendants

45. Distributor Defendants (identified below) have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of the diversion of scheduled, dangerous prescription opioids for non-medical purposes. The Distributor Defendants universally failed to comply with federal and state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law.

46. The Mentasta Tribe alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing the Mentasta Tribe and similarly situated Indian tribes throughout Alaska.

47. Defendant Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with an annual revenue of $121 billion in 2016. Through its various DEA registrant subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

48. Defendant McKesson Corporation ("McKesson") is a Delaware Corporation with its principal place of business in San Francisco, California. McKesson is one of the largest wholesalers of pharmaceutical drugs in the world and distributes prescription opioids throughout the United States.

49. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

50. Defendant Health Mart Systems, Inc. ("Health Mart") is a Delaware corporation with its principal place of business in California. Health Mart operates as a subsidiary of McKesson Corporation. During all relevant times, Health Mart has sold and continues to sell prescription opioids. Health Mart is a franchising and marketing arm that has relationships with 4,700 retail pharmacies nationally.

51. AmerisourceBergen Corporation ("AmerisourceBergen"), through its various DEA registrant subsidiaries and affiliated entities, including but not limited to AmerisourceBergen Drug

Corporation, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with an annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

52. Cardinal, McKesson, and AmerisourceBergen are collectively referred to as the "Distributor Defendants."

Pharmacy Defendants

53. Defendant Walgreen Co. ("Walgreen") is an Illinois business entity with its principal place of business in Illinois. Walgreen is authorized to conduct business throughout the United States. Defendant Walgreen conducts business as a licensed wholesale distributor under the following named business entities: Walgreen Co.; Walgreen Eastern Co., Inc.; Walgreen Arizona Drug Co. (collectively "Walgreens"). At all relevant times, Walgreen, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids at locations throughout the United States that serve Tribal Citizens of the Mentasta Tribe and similarly situated Indian tribes throughout Alaska.

54. Walgreen has been penalized for serious and flagrant violations of the Controlled Substances Act ("CSA"). Indeed, Walgreen agreed to the largest settlement in DEA history - $80 million - to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and to illegal black market sales.

55. Albertsons Companies LLC ("Albertsons") is a Delaware business entity with its principal place of business in Boise, Idaho. Albertsons is authorized to conduct business

throughout some states in the United States as a licensed wholesale distributor, through its various DEA registered subsidiaries and affiliated entities. Albertsons is the parent company of Carrs-Safeway. At all relevant times, Albertsons, through its subsidiaries, distributed prescription opioids at locations throughout Alaska that served the Mentasta Tribe and other similarly situated Alaskan federally recognized Tribes.

56. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc. ("Walmart") is a Delaware corporation with its principal place of business in Arkansas. Walmart is authorized to conduct business throughout some states in the United States. At all relevant times, Walmart, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids throughout Alaska that served the Mentasta Tribe and other similarly situated Alaskan federally recognized Tribes.

57. Defendant CVS Pharmacy, Inc. is a Delaware corporation with its principal place of business in Rhode Island. CVS Pharmacy, Inc. is authorized to conduct business throughout some states in the United States as a licensed wholesale distributor, through its various DEA registered subsidiaries and affiliated entities, including under the following named business entities: CVS Indiana, L.L.C.; CVS Orlando FL Distribution; CVS Pharmacy, Inc.; CVS RX Services, Inc., d/b/a CVS Pharmacy Distribution Center; CVS TN Distribution, LLC; and CVS VERO FL Distribution, L.L.C. (collectively "CVS"). At all relevant times, CVS has distributed prescription opioids at locations throughout Alaska that served the Mentasta Tribe and other similarly situated Alaskan federally recognized Tribes.

58. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or executed by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of

Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

59. The Mentasta Tribe brings this class action in *In Re: National Prescription Opiate Litigation*, MDL 2804, and files directly in the Northern District of Ohio as permitted in Paragraph 6(a) of this Court's Case Management Order No. 1 dated April 11, 2018 (Doc. # 232). Mentasta Tribe reserves the right to have this matter transferred to one or more U.S. District Courts for trial, either as class actions, subclass actions, and/or individual Tribe actions.

60. This Court has subject matter jurisdiction over this action because the Mentasta Tribe brings a federal cause of action that raises federal question jurisdiction pursuant to 28 U.S.C. § 1331. This Court has supplemental jurisdiction over the Mentasta Tribe's state law claims pursuant to 28 U.S.C. § 1367.

61. Defendants' conduct has caused and is causing damages to the Plaintiff's proprietary and sovereign interests by imposing significant costs on the Plaintiff's health and welfare funding and system. In addition, Defendants' conduct has caused decreased economic productivity of Tribal Citizens and non-Tribal Member inhabitants of the Plaintiff's Indian Lands (such as Tribe Member spouses and descendants) and employees of the Plaintiff or wholly-owned enterprises of the Plaintiff and has harmed the long-term health and welfare of the Tribe's Citizens and non-Tribe Member inhabitants of the Plaintiff's Indian Lands (such as Tribe Member spouses and descendants) and employees of the Plaintiff Nation or wholly-owned enterprises of the Plaintiff.

62. Defendants' conduct has caused and is causing a crisis within the Tribe, and other similarly situated Alaskan tribes, that threatens the health, welfare, economic security and political

integrity of the Plaintiff Tribe and all its Citizens. Because of Defendants' actions, certain Citizens of the Tribe have become addicted to prescription opioid drugs, causing severe injury, requiring rehabilitation and medical treatment for substance abuse disorder, causing children to be born addicted to prescription opioids and other controlled substances, and causing short and long term emotional and physical damage that requires treatment, long term care, and in some instances, foster care or adoption. The adverse financial impact on the Plaintiff has been enormous.

63. The negative impacts on the next generation of the Plaintiff's Citizens caused by the conduct of Defendants—in particular, the ruinous effects on the health of the Tribe's children, and the removal of Tribe Citizen children from their parents—threaten the continuation of the Plaintiff's culture, identity, and self-government into the future. The impacts are so severe and cumulatively that Defendants' conduct threatens the entirety of the Tribe.

64. The U.S. District Court, District of Alaska, has personal jurisdiction over Defendants, each of which has substantial contacts and business dealings throughout by virtue of the distribution, dispensing, and sales of prescription opioids within Alaska. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions within Alaska and consequences and damages related to said wrongful actions, conduct, and omissions.

65. The U.S. District Court, District of Alaska, also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and the Plaintiff demonstrates national contacts. Here, the interests of justice require that the Tribe be permitted to bring all members of the nationwide RICO enterprise before the court in a single trial.

66. Venue is proper in the U.S. District Court, District of Alaska, because many of the Defendants' acts and omissions that gave rise to the causes of action of this Complaint occurred

in Alaska. Plaintiff states that but for the Order permitting direct filing into the Northern District of Ohio pursuant to Case Management Order No. 1, dated April 11, 2018, Plaintiff would have filed in the U.S. District Court, District of Alaska.

CLASS ACTION ALLEGATIONS

67. Mentasta Tribe brings all claims as class claims under Rules 23(a)(1)-(4), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure.

68. Plaintiff Mentasta Traditional Council brings all claims on behalf of a proposed class of all federally recognized Indian tribes or Villages located within the borders of the State of Alaska, and all of their Tribal Citizens, descendants, residents, employees, and enterprises ("Alaskan Tribal Class"). The Alaskan Tribal Class is a necessary class primarily because Alaskan Indian tribes are in many pertinent respects distinctive in terms of land and services than the Tribes located within the boundaries of in lower 48 states of the United States. This subclass is defined as:

> Any and all federally recognized Indian tribes in Alaska listed on the Secretary of the Interior's list published at 84 Fed. Reg. 1200 (Feb. 1, 2019) that affirmatively elect to join this class or which are so included by the Court.
>
> This class excludes:
>
> (a) any federally recognized Indian tribes in Alaska that has filed an individual action against Defendants based on the same conduct alleged herein; and (b) any federally recognized Indian tribe in Alaska that does not make a timely election to opt-in to the proposed Class or join in such other manner as determined by the Court.

69. Because members of the Alaskan Tribal Class include very small tribes in membership numbers that are located throughout the State of Alaska, joinder of all members is impracticable. Disposition of the Alaskan Tribal Class's claims in a class action will benefit both the parties and the Court.

70. Common questions of law and fact exist as to all members of the Alaskan Tribal Class. Defendants' misconduct, as alleged herein, is generally applicable to all members of the Alaskan Tribal Class and arose from a common set of acts and omissions by the Defendants that occurred throughout the boundaries of the United States, including in Alaska.

71. The questions of law and fact common to the Alaskan Tribal Class include, but are not limited to:

(a) Whether Defendants knew or should have known that prescription opiates were inappropriate for persons with addiction issues, or with a family history of addiction, or to American Indians/Alaska Natives in general who are more prone to addictive related substances;

(b) Whether Defendants owed a duty to the Alaskan Tribal Class members under federal and state law to not deceptively market the addictive nature of prescription opioids;

(c) Whether Defendants engaged in a conspiracy or conspiracies to promote the sales of opioids into Alaska and/or to Alaska tribes;

(d) Whether Defendants owed a duty to the Alaskan Tribal Class members under federal and state law to not consciously oversupply the market with prescription opioids;

(e) Whether Defendants failed to design and implement appropriate and effective safeguards against the diversion of prescription opioids;

(f) Whether Defendants breached such duties;

(g) Whether Defendants engaged in conduct that violates federal RICO statutes;

(h) Whether Defendants knew or should have educated doctors and the medical community of the dangerous and addictive natures of prescription opioids;

(i) Whether Defendants engaged in conduct that caused a public nuisance for the Alaskan Tribal Class members;

(j) Whether Defendants unjustly enriched themselves to the detriment of Plaintiff and the Class;

(k) Whether Defendants violated the Alaska Unfair Trade Practices and Consumer Protection Act;

(l) the appropriate injunctive and related equitable relief for the Alaskan Tribal Class; and

(m) the appropriate class-wide measure of damages for the Alaskan Tribal Class.

72. The questions of law and fact common to the members of the Alaskan Tribal Class predominate over any questions affecting only individual members, including legal and factual issues relating to liability and damages

73. Plaintiff's claims are typical of the claims of the members of the Alaskan Tribal Class, and Plaintiff will fairly and adequately protect the interests of the Classes. Plaintiff and all members of the Alaskan Tribal Class have suffered similarly due to Defendants' wrongful conduct. Plaintiff's claims arise out of the same common course of conduct giving rise to the claims of the other members of the Alaskan Tribal Class.

74. Plaintiff's interests are coincident with, and not antagonistic to, those of the other members of the Alaskan Tribal Class.

75. Plaintiff is represented by counsel competent and experienced in the prosecution of mass tort litigation of this nature.

76. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, many members of the Alaskan Tribal Class lack the adequate resources, in part due to the opioid crisis, to hire and retain counsel on an individual basis. Proceeding on a class basis will enable the Alaskan Tribal Class members to unify their common interest in combating and abating the opioid epidemic, strengthen their voices, and protect their sovereign rights. The benefits of proceeding as a class, therefore, outweigh any potential difficulties in managing this class action.

FACTUAL ALLEGATIONS

77. Opioid means "opium like" and the term includes all drugs derived in whole or in part from the opium poppy.

78. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

79. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act ("CSA"). They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

80. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

81. To establish and exploit the lucrative market of chronic pain patients, Defendants developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties, to spread false and deceptive statements about the risks and benefits of long-term opioid use — statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including that of the Mentasta Tribe and similarly situated Indian tribes throughout Alaska.

82. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and residents of the Mentasta Tribe and similarly situated Indian tribes throughout Alaska. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the United States.

83. Defendants' direct and branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Endo agreed in 2015-16 to stop these particularly misleading representations in New York but continued to disseminate them in other parts of the United States.

84. Defendants also promoted the use of opioids for chronic pain through "detailers" — sophisticated and specially trained sales representatives who visited individual doctors and medical staff and fomented small-group speaker programs. In 2014, for instance, Defendants spent almost $200 million on detailing branded opioids to doctors.

85. The FDA has cited at least one Defendant for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

86. Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed

misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

87. Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

88. Defendants have had unified marketing plans and strategies from state to state. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

89. Defendants deceptively marketed opioids throughout the United States through unbranded advertising that promoted opioid use generally yet was silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by Defendants and their public relations firms and agents.

90. Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. Defendants used third-party, unbranded advertising to create the false appearance that the deceptive messages came from an independent and objective source.

91. Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

92. Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders"

or "KOLs." Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

93. Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG") (collectively referred to as "Front Groups").

94. Defendants collaborated, through the aforementioned organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

95. To convince doctors and patients throughout the United States that opioids can and should be used to treat chronic pain, Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by, or were contrary to, the scientific evidence and which were contradicted by data.

96. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations—which are described below—reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction

could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations; they continue to make them today.

97. Defendants falsely claimed that the risk of opioid addiction is low; that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these false and deceptive claims by opioid manufacturers are:

98. Endo falsely represented that addiction is rare in patients who are prescribed opioids.

99. Until April 2012, Endo's website for Opana, *www.opana.com*, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

100. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.

101. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"). Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on

Pain Control ("NIPC") and its website *www.painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

102. Another Endo website, *www.PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

103. A brochure available on *www.painknowledge.com* titled *"Pain: Opioid Facts,"* Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

- In a patient education pamphlet titled "Understanding Your Pain: Taking Oral Opioid Analgesics," Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

104. An Endo publication, *Living with Someone with Chronic Pain*, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.

105. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction."

106. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."

107. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.

108. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient' s fear that "I' m afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

109. Cephalon sponsored and facilitated the development of a guidebook, Opioid Medications and REMS: A Patient's Guide, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's Treatment Options: A Guide/or People Living with Pain (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

110. For example, a 2003 Cephalon-sponsored CME presentation titled Pharmacologic Management of Breakthrough or Incident Pain, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population…… The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fears of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse

> behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.

111. Through its "Learn More about customized pain control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

112. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (a) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (b) repeatedly emphasizing the difference between substance dependence and substance abuse; and (c) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the under treatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

113. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

114. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the

following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse-deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

115. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

116. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

117. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled Defeat Chronic Pain Now! The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line**: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

118. In a 2013 Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

119. Manufacturer Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they

are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

120. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

121. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

122. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers

meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but there was no evidence to support that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. This agreement, however, did not extend throughout the United States.

123. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" — a term used by Dr. David Haddox and Dr. Russell Portenoy, a KOL for Cephalon, Endo, and Janssen. Defendants falsely claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these deceptive claims are:

124. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

125. Upon information and belief, Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

126. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when pain is *undertreated* Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012.

127. Janssen also currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases."

128. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a so-called "key opinion leader" (KOL) discussed below, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

129. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

130. Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These

misrepresentations were reckless because Manufacturer Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. For an example of one of these deceptive claims, an Endo supplement in the *Journal of Family Practice* emphasized the effectiveness of screening tools to avoid addictions.

131. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse — "for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

132. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

133. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by

intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

134. Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

135. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and

lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated: "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."; (b) Cephalon sponsored *APF's Treatment Options: A Guide for People Living with Pain*, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain"; (d) an Endo pamphlet, *Understanding Your Pain: Taking Oral Opioid Analgesics*, stated "The dose can be increased. . . . You won't 'run out' of pain relief"; (e) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages.

136. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

137. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose

and/or overdose mortality."

138. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturer Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

139. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

140. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *www.opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

141. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva and Endo, taught that relief of pain by opioids, by itself, improved patients' function.

142. In addition, Janssen's *Let's Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

143. Endo's NIPC website *www.painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

144. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

145. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

146. The Manufacturer Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life. Based upon a review of the existing scientific evidence, the

CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."

147. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have shown that opioids for chronic pain may actually worsen pain and functioning . . ." along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

148. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant." According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."

149. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." In fact, research such as a 2008 study in the journal Spine has shown that pain sufferers prescribed opioids long-term suffered addiction that made

them more likely to be disabled and unable to work. Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all. Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was recently published on March 6, 2018, in the Journal of the American Medical Association. The study reported that "[t]here was no significant difference in pain-related function between the 2 groups" – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen. Accordingly, the study concluded: "Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."

150. In materials they produced, sponsored or controlled, the Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

151. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturer Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;" hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with

benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.

152. The APF's Treatment Options: *A Guide for People Living with Pain*, sponsored by Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.

153. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), which listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

154. Endo's NIPC website, *www.painknowledge.com*, which contained a flyer called "*Pain: Opioid Therapy*." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

155. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and

does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

156. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "*Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*." The article asserted:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

157. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

158. Additionally, Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

159. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." The 2016 CDC Guideline states that NSAIDs, not opioids, should

be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

160. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

161. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) In December 2011, Cephalon widely disseminated a journal supplement

entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News*—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" —and not just cancer pain.

162. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain but were also approved by the FDA for such uses.

163. As a result of the Manufacturer Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.

164. Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

165. Manufacturer Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous

abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

166. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State of New York found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

167. Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

168. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations throughout the U.S., including in Mentasta Tribe's areas. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

169. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline, therefore, concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

170. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo has recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

171. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

172. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Defendants, such as Janssen, ran similar websites that masked their own direct role.

173. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions.

174. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Mentasta Tribe now asserts. The Mentasta Tribe did not know of the existence or scope of Defendants' industry-

wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

175. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

176. Defendants' deceptive marketing scheme caused and continues to cause doctors throughout the country to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

177. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

178. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic

increase in opioid addiction, overdose, and death throughout the U.S. In August 2016, the U.S. Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

179. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

180. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers, or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

181. The supply chain for prescription opioids to the consumer from the manufacture begins with the distribution of pills to the Distributor Defendants, which together account for 85-90% of all revenues from drug distribution in the United States, an estimated $378.4 billion in

2015. The distributors then supply opioids to hospitals, pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

182. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs when the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

183. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

184. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (a/k/a doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other "red flags" surrounding the transaction. These signs or "red flags" should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the

medication for purposes to treat a legitimate medical condition. In addition to diversion via prescription, opioids are also diverted from retail outlets when stolen by employees or others.

185. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

186. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

187. Every year, millions of people in the United States misuse and abuse opioid pain relievers that can lead to addiction, overdose, and death. The overdose rate among American Indians is significantly higher than the rest of the population.

188. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids are at epidemic proportions, quadrupling since 1999, concomitant with sales of these prescriptions.

189. In 2011 overdose deaths from prescription opioids reached 16,917 people. In 2014 18,893 people died from a prescription opioid-related overdose. In 2015, the number of deaths increased to 22,598, even despite increased public health announcements.

190. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that

people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin. Heroin deaths are on a tragic upswing: In 2015, over 12,989 people died from heroin overdose - up more than 20% from approximately 10,574 overdose deaths in 2014.

191. The Mentasta Tribe and similarly situated Indian tribes throughout Alaska have taken proactive measures to fight against prescription opioid abuse, but such measures have not deterred Defendants' conduct.

192. American Indians, in general, are more likely than other racial/ethnic groups in the United States to die from drug-induced deaths. Like other federally recognized Indian tribes, the Mentasta Tribe has been hit by the effects of Defendants' opioid diversion.

193. The CDC reports that for every opioid-related death, there are on average 10 hospital admissions for abuse, 26 emergency department visits for misuse, 108 people who are dependent on opioids, and 733 non-medical users.

194. The impact on the American Indian children has been devastating. It has been reported that by 12th grade, nearly 13 percent of American Indian teens have used OxyContin, one of the deadliest opioids when misused. The use of OxyContin by American Indian 12th-graders was about double the national average.

195. A 2014 study funded by the National Institute on Drug Abuse found a much higher prevalence of drug and alcohol use in the American Indian 8th and 10th graders compared with national averages. American Indian students' annual heroin and OxyContin use was about two to three times higher than the national averages in those years.

196. The fact that American Indian teens are easily able to obtain OxyContin at these alarming rates indicates the degree to which opioid diversion has created an illegal secondary market for opioids.

197. It has been reported that pregnant American Indian women are up to 8.7 times more likely to be diagnosed with opioid dependence or abuse compared to the next highest race/ethnicity. It has been reported that in some communities, upwards of 1 in 10 pregnant American Indian woman has a diagnosis of opioid dependence or abuse. On information and belief, these statistics apply similarly to pregnant women who are Tribal Citizens or the mothers of Tribal Citizens or their descendants.

198. Many of the parents of these Tribal Citizens children continue to relapse into prescription opioid use and lose custody of the children. As a result, many of these children are placed in foster care or adopted.

199. Defendants' opioid diversion in and around lands occupied by the Mentasta Tribe and similarly situated Indian tribes throughout Alaska contributes to a range of social problems including physical and mental consequences, crime, delinquency, and mortality. Adverse social outcomes include child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more tribal resources are devoted to addiction-related problems, leaving a diminished pool of available resources to devote to positive societal causes like education, elder care, health care, early child development, cultural preservation, and social programs. Meanwhile, the prescription opioid crisis diminishes the Mentasta Tribe and similarly situated Indian tribes throughout Alaska' available workforce, decreases productivity, increases poverty, and consequently requires greater government assistance expenditures.

200. The Mentasta Tribe and similarly situated Indian tribes throughout Alaska are affected by highly-addictive opioid painkillers diverted from Defendants' supply chains, thereby ensuring that the Tribal Citizens will continue to suffer from addiction rates higher than national

averages and, commensurately, that Defendants will continue to profit by supplying opioids to the area. This civil lawsuit is the only remaining weapon to fight against the worsening opioid abuse epidemic that Defendants have caused to the Mentasta Tribe, Tribal Citizens, non-Tribal Member inhabitants (such as Tribal member spouses and descendants), and employees of the Mentasta Tribe and other similarly situated Indian tribes throughout Alaska or wholly-owned enterprises of said tribes.

201. Contrary to the assertions by many of the Distributor Defendants that they were only disinterested distributors of prescription opioids and had no role in marketing and promoting those drugs, documents obtained have revealed the opposite to be true. Distributor Defendants, including the "Big Three," AmerisourceBergen, Cardinal Health, and McKesson, have participated in the Manufacturer Defendants ' promotion of prescription opioids and have even entered into contractual agreements providing them monetary remuneration for doing so.

202. Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

203. In addition to having common law duties, the Distributor Defendants are governed by certain statutory requirements of the CSA. These requirements were enacted to protect society from the harms of drug diversion.

204. The CSA creates a legal framework for the distribution and dispensing of controlled substances, which includes requirements for registration with and reporting to the Department of

Justice ("DOJ") in order to establish a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user.

205. For years the Defendants have known of the problems and consequences of opioid diversion in the supply chain.

206. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

207. Distributor Defendant Cardinal specifically proposed marketing initiatives to opioid manufacturers to promote and facilitate more sales of prescription opioids.

208. Likewise, Distributor Defendant McKesson utilized its pharmaceutical marketing department to work with the manufacturers to actively promote opioids.

209. Documents produced by the Manufacturer Defendants further indicate that opioid manufacturers coordinated their opioid marketing messaging with the Distributor Defendants, including AmerisourceBergen, Cardinal, and McKesson, who were publishing promotional material regarding opioids.

210. The Manufacturer Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

211. Defendants' distribution of opioids was driven by national policies, coordination, plans, and procedures that were the same in Plaintiff's State as they were across the country. Distributor Defendants worked together in an illicit enterprise, engaging in conduct that was not

only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict. At all relevant times, Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. Defendants utilized this data to further their distribution scheme and to ensure the largest possible financial return.

212. For over a decade, as the Manufacturer Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

213. Defendants are all required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

214. Manufacturer Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often, first-line treatment. Manufacturer Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales,

today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

215. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

216. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity" (emphasis added).

217. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country." These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

218. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

219. The Distributor Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the federal Drug Enforcement Agency ("DEA") related to violations of the federal Controlled Substances Act.

220. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a U.S. Department of Justice press release announced a multi-million-dollar settlement with Cardinal for violations of the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

221. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of

controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

222. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

223. State Boards of Pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion.

224. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

225. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable danger of serious injury to the Mentasta Tribe and its Tribal Citizens.

226. The Distributor Defendants have supplied massive quantities of prescription opioids within the economic proximity of the Mentasta Tribe with the actual or constructive

knowledge that the opioids were ultimately being consumed by Tribal Citizens and employees of the Plaintiffs or wholly-owned enterprises of the Plaintiffs for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

227. Each Distributor Defendant knew or should have known that the amount of opioids that it allowed to flow into the Plaintiffs' Tribal communities and surrounding areas was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

228. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the Mentasta Tribe; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

229. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies within the economic proximity of the Mentasta Tribe, servicing the Tribal

Citizens, to perform due diligence inspections to ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

230. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the Mentasta Tribe thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

231. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around the Mentasta Tribe with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

232. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by the Mentasta Tribe's members, and that the costs of these injuries will be borne by the Mentasta Tribe.

233. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic within the Mentasta Tribe, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

234. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed within the economic proximity of the Mentasta Tribe were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third parties, and the Mentasta Tribe.

235. The Distributor Defendants were aware of widespread prescription opioid abuse in and around the Mentasta Tribe, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

236. The use of opioids by Tribal Citizens who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If any of the Distributor Defendants adhered to effective controls to guard against diversion, significant injury could have been avoided.

237. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into the Mentasta Tribe. Their participation and cooperation in a common enterprise has foreseeably caused injuries and financial damages to the Mentasta Tribe and its members. The Distributor Defendants knew full well that the Mentasta Tribe would be unjustly forced to bear the costs of these injuries and damages.

238. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to a relatively small community in and around the Mentasta Tribe showed an intentional or reckless disregard for the safety of the Mentasta Tribe and its members. Defendants' conduct poses a continuing threat to the health, safety, and welfare of the Mentasta Tribe.

239. Pharmacies must exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

240. Pharmacies are the "last line of defense" in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system and as such, have considerable duties and responsibility in the oversight of patient care. They cannot blindly fill prescriptions written by a doctor, even one registered in the DOJ's Controlled Substances Utilization Review and Evaluation System ("CURES") database, if the prescription is not for a legitimate medical purpose.

241. The CSA imposes duties and requirements on the conduct of the Pharmacy Defendants. These requirements set a standard of care for pharmacy conduct. Under the CSA, the Pharmacy Defendants are required to maintain records and report information on Schedule II controlled substance prescriptions to the DOJ.

242. Pharmacists are required to ensure that prescriptions for controlled substances are valid and must not fill prescriptions that are not written on the required tamper-resistant forms that are available to practitioners only from secure state-approved printers, pursuant to the CSA. Pharmacists are the last check in the opioid distribution industry. Pharmacists are to ensure that prescriptions are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

243. Pharmacy boards, national industry associations, and continuing education programs have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

244. The industry guidance tells pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor's name, but with a different call back number

that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on.

245. Questionable or suspicious prescriptions include: prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances compared to other practitioners in the area; prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; prescriptions that look "too good" or where the prescriber's handwriting is too legible; prescriptions with quantities or dosages that differ from usual medical usage; prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; photocopied prescriptions; or prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; rather, they should be apparent to an adequately trained pharmacist.

246. Signs that a customer is seeking opioids for the purpose of diversion include customers who: appear to be returning too frequently; are seeking to fill a prescription written for a different person; appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; are not regular patrons or residents of the community, and show up with prescriptions from the same physician; drive long distances to have prescriptions filled; seek large volumes of controlled substances in the highest strength in each prescription; seek a combination of other drugs with opioids such as tranquilizers and muscle relaxers that can be used to create an "opioid cocktail"; and pay large amounts of cash for their prescriptions rather than using insurance. Ignoring these signs violates industry standards and DEA guidelines.

247. Other "red flags" include when prescriptions that lack the technical requirements of a valid prescription, such as a verifiable DEA number and signature; prescriptions written in excess of the amount needed for proper therapeutic purposes; prescriptions obtained through disreputable or illegal web-based pharmacies; and patients receiving multiple types of narcotic pain killers on the same day.

248. All of these issues have been presented by the DEA in pharmacist training programs throughout the United States and have been used as examples by individual state boards of pharmacy and the National Association of Boards of Pharmacy.

249. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. If a pharmacist is ever in doubt, he or she must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she should not dispense it and call the local police. If a pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

250. A standard of care for the Pharmacy Defendants is also set by applicable most professional regulations throughout the country. It is a violation of professional standards not to attempt to address the suspected addiction of a patient to a drug dispensed by the pharmacist, if there is reason to believe the patient may be addicted.

251. On information and belief, the Pharmacy Defendants regularly filled prescriptions in circumstances where red flags were present (and sometimes many red flags).

252. On information and belief, the Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably prudent pharmacy.

253. On information and belief, the Pharmacy Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

254. On information and belief, the Pharmacy Defendants utilize monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and dispensed. This type of compensation creates economic disincentives within the companies to change their practices. For example, there have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of the red flags presented.

255. The Pharmacy Defendants have violated a voluntarily undertaken duty to the public which they have assumed by their own words and actions. In news reports and other public documents, it has been reported that the Pharmacy Defendants, through their words or actions, have assured the public that issues affecting public health and safety are the highest priority for the defendants.

256. The Pharmacy Defendants Pharmacies have long been on notice of their failure to abide by state and federal laws and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Pharmacy Defendants Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Pharmacy Defendants Pharmacies.

257. For example, CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing

business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

258. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

259. This fine was preceded by numerous others throughout the country.

260. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

261. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

262. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

263. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances— mostly addictive painkillers—more than 500 times between 2011 and 2014.

264. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

265. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for

improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

266. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

267. In 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a Nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under state and federal law to determine whether a controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."

268. In failing to take adequate measures to prevent substantial opioid-related injuries to the Mentasta Tribe and its members, the Pharmacy Defendants have breached their duties under the "reasonable care" standard, professional duties under the relevant standards of professional practice, and requirements established by professional law throughout the United States.

269. It is foreseeable to the Pharmacy Defendants that filling invalid or suspicious prescriptions for opioids would cause harm to individual pharmacy customers, including Tribal Citizens who may use the wrongfully dispensed opioids, and would also harm the Tribal government and enterprises owned by the Mentasta Tribe which are designed to provide revenue back to the government to fund government programs and provide for the general welfare of the Tribe.

270. It is reasonably foreseeable to the Pharmacy Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including overdoses and death.

It is also reasonably foreseeable many of these injuries will be suffered by the Mentasta Tribe and its Tribal Citizens.

271. At all relevant times, the Pharmacy Defendants have engaged in improper dispensing practices, and continue to do so, despite knowing full well they could take measures to substantially eliminate their complicity in opioid diversion.

272. At all relevant times, the Pharmacy Defendants engaged in these activities, and continue to do so, knowing full well that the Mentasta Tribe, in their role of providing protection and care for their members, would provide or pay for additional medical services, emergency services, law enforcement, and other necessary services, as well as compensate for the loss of substantial economic productivity that contributes to the health and well-being of the Mentasta Tribe.

273. It is reasonably foreseeable to the Pharmacy Defendants that the Mentasta Tribe would be forced to bear substantial expenses as a result of the Pharmacy Defendants' acts.

274. The Pharmacy Defendants were on notice of their ongoing negligence or intentional misconduct towards the Mentasta Tribe in part because of their history of being penalized for violating their duties and legal requirements in other jurisdictions.

275. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.

276. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids

into illicit channels.

277. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

278. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.

279. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by the number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

280. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

281. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

282. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

283. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from Pharmacy Defendants Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

284. The litany of state and federal actions against the Pharmacy Defendants Pharmacies demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

285. Throughout the country and in within the area served by the Tibe, in particular, the Pharmacy Defendants Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

286. On information and belief, from the catbird seat of their retail pharmacy operations, the Pharmacy Defendants Pharmacies knew or reasonably should have known about the

disproportionate flow of opioids into the State and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

287. On information and belief, the Pharmacy Defendants Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

288. On information and belief, because of (among other sources of information) regulatory and other actions taken against the Pharmacy Defendants Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Pharmacy Defendants Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

289. The Pharmacy Defendants Pharmacies' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

COUNT I
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961 et seq.

290. The Mentasta Tribe re-alleges and incorporates by reference the foregoing paragraphs.

291. Defendants conducted and continue to conduct their business through illegitimate means in an association-in-fact enterprise and/or legal entity enterprise.

292. Defendants are persons under 18 U.S.C. § 1961(3) because they are entities holding a legal or beneficial interest in property.

293. Defendants have aggressively sought to increase and generate profits from the prescription opioid market by unlawfully increasing the volume of opioids manufactured, distributed, and sold.

294. As registrants under the CSA, Defendants are not permitted to limitlessly expand the opioid market through unlawful sales of regulated prescription opioids.

295. The CSA restricts and regulates Defendants' ability to manufacture and distribute prescription opioids, requiring Defendants to maintain effective preventative measures against opioid diversion, including, but not limited to: monitoring and identifying suspicious orders, preventing suspicious order from being filled, reporting suspicious orders to the DEA, and to not exceed sales quotas established by the DEA.

296. These precautionary methods created by the CSA were intentionally established to reduce or eliminate the potential for opioid diversion.

297. The Defendants found it impossible to maximize profits within the legal framework of the CSA. Choosing illegal profits over the law, Defendants systematically and fraudulently violated their statutory duties of maintaining effective anti-diversion measures through the intentional failure to report suspicious orders and the repeated unlawful sales of prescription opioids. As a result, Defendants illegally increased the annual production quotas for prescription opioids.

298. The term "enterprise" is defined as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The definition of "enterprise" in § 1961(4) includes both

legitimate and illegitimate enterprises.

299. Manufacturer Defendants and Distributor Defendants forged an association-in-fact enterprise to perpetrate their illegal scheme of illegally increasing the production of prescription opioids (collectively referred to as the "Opioid Diversion Enterprise"). In concert and through the Opioid Diversion Enterprise, Defendants participated in an illegal scheme, the purpose of which was to engage in the unlawful sale of prescription opioids while deceiving the public and regulators into believing that Defendants were faithfully complying with their statutory obligations. The Opioid Diversion Enterprise enabled Defendants to profit billions of dollars in the unlawful sale of opioids. As a direct result of Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, Defendants were able to extract billions of dollars in profit from millions of addicted Americans and Plaintiffs' Tribal Citizens, while entities such as the Mentasta Tribe and similarly situated experienced millions of dollars in damages caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

300. Defendants formed an additional association-in-fact enterprise to unlawfully market the safety and efficacy of prescription opioids (collectively referred to as the "Opioids Promotion Enterprise"). The Opioids Promotion Enterprise is comprised of Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOLs; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioids Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market opioids as scientifically proven as safe and effective.

301. The Opioids Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioids Promotion Enterprise was created and organized to

effectuate a pattern of racketeering activity and maintained systematic links for a common purpose: to ensure the continued prescription of opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioids Promotion Enterprise.

302. The Opioids Promotion Enterprise and Opioids Diversion Enterprise scheme empowered Defendants to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent schemes, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while the Mentasta Tribe suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. The Mentasta Tribe is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

303. Members of the Opioid Diversion Enterprise systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As alleged herein, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

304. Alternatively, Defendants were also members of a legal entity enterprise. The Healthcare Distribution Alliance ("HDA") is a distinct legal entity that qualifies as an enterprise under 18 U.S.C. § 1961(4). The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia.

305. The Defendants utilized the HDA to conduct a RICO enterprise and to engage in the pattern of racketeering activity that gives rise to the RICO Count.

306. Each of the Defendants is a legal entity separate and distinct from the HDA, and the HDA serves the interests of distributors and manufacturers beyond the Defendants.

307. Therefore, the HDA exists separately from the Opioid Diversion Enterprise and the Opioid Promotion Enterprise and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

308. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the HDA were each used by the Defendants to engage in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are collectively referred to as the "RICO Enterprise."

309. It is unlawful for a CSA registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

310. At all relevant times, the Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

311. At all relevant times, the RICO Enterprise: (a) existed separately and distinctly from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the

Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astonishing growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

312. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion.

313. Members of the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties.

314. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the United States and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

315. The Defendants colluded to ensure that the quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious

orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the HDA;

b. The Distributor Defendants invited the participation, oversight, and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

f. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

g. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders;

h. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA;

i. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

316. Defendants took intentional and affirmative steps to conceal the RICO scheme through the use of unbranded advertisements, third parties, and the Front Groups to disguise the source of the Defendants' fraudulent statements.

317. Each time a participant in the illegal RICO scheme distributed a false statement by mail or wire, it committed a separate act of mail fraud or wire fraud under federal law, thereby demonstrating a pattern of racketeering activity.

318. Defendants used and caused to be used thousands of interstate mail and wire communications through uniform misrepresentations, concealments, and material omissions regarding the safety and efficacy of opioids and their compliance with the CSA's anti-diversion statutes. The Defendants committed this pattern of racketeering activity on a continual and regular basis with the intent to advance the illegal scheme of the RICO Enterprise.

319. Defendants also engaged in a pattern of racketeering activity in the unlawful manufacture, distribution, and sale of prescription opioids, a controlled substance under the CSA. Defendants routinely and intentionally furnished false, misleading, or incomplete information in their reports to the DEA and in their applications for production quotas.

320. The Mentasta Tribe has injuries that were directly caused by the Defendants' racketeering activities.

321. The Mentasta Tribe was most directly harmed and there are no other entities better suited to seek a remedy for the economic harms at issue here.

322. The Mentasta Tribe, individually and on behalf of the Alaskan Tribal Class, seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT II
NUISANCE

323. The Mentasta Tribe re-alleges and incorporates by reference the foregoing paragraphs.

324. The nuisance is the over-saturation of opioids within the economic proximity of the Mentasta Tribe, and to Tribal Citizens, for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

325. All Defendants substantially participated in nuisance-causing activities.

326. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids from premises around the Mentasta Tribe to unintended users in the Mentasta Tribe—including children, people at risk of overdose or suicide, and criminals.

327. Defendants' nuisance-causing activities also include failing to implement effective

controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

328. Defendants' activities unreasonably interfere with the following common rights of the Tribal Citizens:

a. To be free from reasonable apprehension of danger to person and property;

b. To be free from the spread of disease within the community including the disease of addiction and other diseases associated with widespread illegal opioid use;

c. To be free from the negative health and safety effects of widespread illegal drug sales on premises in and around the Mentasta Tribe;

d. To be free from blights on the community created by areas of illegal drug use and opioid sales;

e. The right to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and to foster a secondary market of illegal transactions; and

f. The right to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

329. The Defendants' interference with these rights of the Mentasta Tribe is unreasonable because it:

a. Has harmed and will continue to harm the public health and public peace of the Mentasta Tribe;

b. Has harmed and will continue to harm the Mentasta Tribe's communities by increasing the levels of vagrancy, and property crime, and thereby interfering with the rights of the Tribal community at large;

c. Is of a continuing nature, and it has produced a long-lasting effect; and

d. Defendants have reason to know their conduct has a significant effect upon the public rights of the Mentasta Tribe and their Tribal Citizens.

330. Public resources are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources that could be used to benefit the Mentasta Tribe at large.

331. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

332. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the surrounding Tribal community. Distributor Defendants had the power to shut off the supply of illicit opioids into the Mentasta Tribe.

333. As a direct and proximate result of the nuisance, Tribal Citizens have suffered in their ability to enjoy rights of the public.

334. As a direct and proximate result of the nuisance, the Mentasta Tribe has sustained economic harm by spending a substantial amount of money trying to fix the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, and law enforcement.

335. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

336. Defendants should be required to abate the nuisance and/or pay the expenses the Mentasta Tribe has incurred or will incur in the future to fully abate the nuisance, and punitive damages.

337. The Mentasta Tribe, individually and on behalf of the Alaskan Tribal Class, seeks any and all relief available under this Count II.

COUNT III
NEGLIGENCE AND GROSS NEGLIGENCE

338. The Mentasta Tribe re-alleges and incorporates by reference the foregoing paragraphs.

339. Defendants owe a non-delegable duty to the Mentasta Tribe to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

340. There is no social value to Defendants' challenged behavior. In fact, Defendants' behavior is against the law; i.e., facilitating the diversion of opioids to the illicit black market.

341. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of the Mentasta Tribe and its members.

342. There is an extremely high likelihood of Defendants' behavior causing a substantial injury to the Mentasta Tribe's interests. The harmful consequences of opioid diversion are apparent from the statistics related to prescription opioid overdoses and deaths.

343. Defendants' conduct fell below the reasonable standard of care. Their negligent acts include:

a. Consciously oversupplying the market in and around the Mentasta Tribe with highly-addictive prescription opioids;

b. Using unsafe distribution and dispensing practices;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Inviting criminal activity into the Mentasta Tribe by disregarding precautionary measures built into the CSA, pharmacy board regulations, and applicable law;

e. Failing to properly train or investigate their employees;

f. Failing to properly review prescription orders for red flags;

g. Failing to report suspicious orders or refuse to fill them;

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and

i. Failing to police the integrity of their supply chains.

344. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

345. Each Defendant sold prescription opioids in the supply chain knowing both that (1) there was a substantial likelihood many of the sales were for non-medical purposes, and (2) opioids are an inherently dangerous product when used for non-medical purposes.

346. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

347. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

348. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

349. Defendants are in a limited class of registrants authorized to legally distribute controlled substances to, among, and within the economic proximity of the Mentasta Tribe. This places Defendants in a position of great trust and responsibility vis-a-vis the Mentasta Tribe. Defendants owe a special duty to the Mentasta Tribe: the duty owed cannot be delegated to another party.

350. The Mentasta Tribe is without fault, and the injuries to the Mentasta Tribe and its members would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

351. The aforementioned conduct of Defendants proximately caused damage to the Mentasta Tribe, including increased healthcare and law enforcement costs, lower tax revenue, and lost productivity.

352. The Mentasta Tribe, individually and on behalf of the Alaskan Tribal Class, seeks any and all relief available pursuant to this Count III.

COUNT IV
UNJUST ENRICHMENT

353. The Mentasta Tribe re-alleges and incorporates by reference the foregoing paragraphs.

354. The Mentasta Tribe has expended substantial amounts of money to fix or mitigate the societal harms caused by Defendants' conduct.

355. The expenditures by the Mentasta Tribe in providing healthcare services to people who use opioids have added to Defendants' wealth. The expenditures by the Mentasta Tribe have helped sustain Defendants' businesses.

356. The Mentasta Tribe has conferred a benefit upon Defendants by paying for what may be called Defendants' externalities—the costs of the harm caused by Defendants' negligent distribution and sales practices.

357. Defendants are aware of this obvious benefit, and retention of this benefit is unjust.

358. Defendants made substantial profits while fueling the prescription drug epidemic in the Mentasta Tribe's community.

359. Defendants continue to receive considerable profits from the distribution of controlled substances in and around Mentasta Tribe's Indian Lands.

360. Defendants have been unjustly enriched by their negligent, intentional, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing.

361. It would be inequitable to allow Defendants to retain this benefit or financial advantage.

362. The Mentasta Tribe, individually and on behalf of the Alaskan Tribal Class, demands judgment against each Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

COUNT V
AS TO MANUFACTURER DEFENDANTS
COMMON LAW FRAUD

363. The Mentasta Tribe re-alleges and incorporates by reference the foregoing paragraphs.

364. Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

365. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following: (a) false patient education materials; (b) advertising the ability of opioids to improve function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use for high- risk patients; (d) Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (g) secretly funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addiction in the elderly; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life, while concealing contrary data; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction; (m) manipulation of data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and (n) in-person detailing.

366. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following: (a) patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious, and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain; and (k) in-person detailing.

367. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements minimizing the risk of addiction of opioids, promoting the concept of pseudo-addiction, advocating the use of opioids for chronic non-cancer pain, funding misleading CMEs, KOL doctors, and pain organizations, minimizing the addictiveness of Cephalon's potent rapid-onset opioids, and promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

368. Defendants Actavis and Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following: (a) promotion of use of opioids to treat chronic non-cancer pain to prescribers throughout the United States through in-person detailing;

(b) advertising that opioids were safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improved quality of life; (c) advertising that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.

369. These false representations and concealments were reasonably calculated to deceive prescribing physicians in the patient areas of the Mentasta Tribe, were made with the intent to deceive, and did, in fact, deceive physicians who prescribed opioids for chronic pain.

370. But for these false representations and concealments of material fact, the Mentasta Tribe would not have incurred excessive costs and economic loss.

371. As a direct and proximate cause of Defendants' fraudulent conduct, the Mentasta Tribe has suffered damages and seeks any and all available relief, individually and on behalf of the Alaskan Tribal Class.

COUNT VI
CIVIL CONSPIRACY

372. The Mentasta Tribe re-alleges and incorporates by reference the foregoing paragraphs.

373. The Distributor Defendants continuously supplied prescription opioids to the Pharmacy Defendants despite having actual or constructive knowledge that said pharmacies were habitually breaching their common law duties.

374. Without the Distributor Defendants' supply of prescription opioids, the Pharmacy Defendants would not be able to fill and dispense the increasing number of prescription opioids throughout the Mentasta Tribe.

375. The Pharmacy Defendants continuously paid the Distributor Defendants to supply large quantities of prescription opioids in order to satisfy the demand for the drugs.

376. Neither side would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party.

377. As a result of the concerted action between the Distributor Defendants and the Pharmacy Defendants, the Mentasta Tribe and its members and the Alaska Class have suffered damage.

378. The Mentasta Tribe, individually and on behalf of the Alaskan Tribal Class, demands judgment against each Defendant for compensatory and punitive damages.

PRAYER FOR RELIEF

Wherefore, premises considered, the Mentasta Traditional Council, individually and on behalf of the Alaskan Tribal Class, prays that the Court grant the following relief against all Defendants, individually, jointly, and severally as follows:

a. Class certification of the Alaskan Tribal Class, with the Attorneys listed below designated as class counsel;

b. Injunctive Relief, including abatement of the nuisance, as against the Defendants for their wrongful, tortious, and illegal activities as alleged hereinabove;

c. Compensatory, consequential, and incidental damages;

d. All available equitable remedies, including restitution and disgorgement of revenue and profits;

e. Punitive damages;

f. Attorneys' fees and all costs and expenses related to this civil action;

g. All such other relief this Court and/or the jury deems just and fair; and

h. Trial by jury for all counts so triable.

Dated this 16th day of January 2020.

Respectfully Submitted,

MENTASTA TRADITIONAL COUNCIL

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